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Korea, Republic of FAIRS Product Specific KFDA Monitoring of Harmful Substances 2007

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Report Highlights:

In 2006, KFDA introduced a program for monitoring harmful substances for which no set standards had been established. Despite the fact that this was only intended to be a monitoring program, voluntary recalls were issued for nine products. In 2007, KFDA will strengthen this program so that violators may receive additional administrative actions or recalls. The appendix lists all of the harmful substances included in this program and KFDA's recommended criteria.

Includes PSD Changes: No Includes Trade Matrix: No Unscheduled Report Seoul [KS1] [KS] In 2006, KFDA introduced a program for monitoring harmful substances for which standards had not been established. As part of "the feel-safe food safety management system", KFDA wanted to strengthen the monitoring and testing of these harmful substances. This program was intended to prevent harmful materials from causing problems in advance and sets up a monitoring system that could be used to establish standards in the future. In March 2007, KFDA announced the 2006 monitoring results and released its plan for 2007.

Results of the 2006 Monitoring Program

In 2006, KFDA tested a total 3,352 items, including both imported and domestically marketed products. Forty-six products exceeded the recommended criteria and based upon the testing results, these products were classified under three categories: Class I, Class II, and Class III.

Classification	Action Required	Examples Of Products That Exceeded The Recommended Criteria
Class I	Needs immediate action	Red pepper (Aflatoxin B1), Olive oil (Benzopyrene), Other infant formula (E. sakazakii)
Class II	Needs continuous monitoring	Hardened oil (trans fatty acid), Tofu (coliforms), Agricultural products (lead and cadmium), Candies (lead), Grain and dried grapes (ochratoxin), Dried red pepper and black pepper inner parts, shredded dried red pepper (Aflatoxin B1)
Class III	Removed from close monitoring	Others

For the forty-six products that exceeded KFDA's recommendations, the importers and manufacturers were given suggestions on how they could correct the problems. But for nine products that were classified as Class I, they were required to issue voluntary recalls. Based upon these results, KFDA will propose or already has proposed new standards. The table below lists those substances for which KFDA has already proposed standards:

Harmful Substances	_Timeline for Establishing Standards
Lead and cadmium standards in ten agricultural	Finalized on December 21, 2006
products including rice	
Benzopyrene standards in olive oil and	Finalized on May 7, 2007
oxytetracycline in honey	
Enterobacter sakazakii standards in food for	Finalized on May 23, 2007
infants younger than 6 months	
Aflatoxin B1 standards in red pepper powder, red	Proposed on April 12, 2007
pepper paste, and bean paste	
Benzopyrene standards in all edible oil & fat	Proposed on May 2, 2007

Revision of Monitoring Program for 2007

For 2007, KFDA established recommended criteria for 14 harmful substances in 40 food products. Based upon the experience with the 2006 program, KFDA felt it necessary to revise the program. They will now publicly release the testing results and continue to require voluntary recalls. Unlike the previous year, in 2007, harmful substances will be limited to those substances where standards have been proposed or will be proposed shortly.

According to the revised program, KFDA headquarters will select the harmful substances through consultations with the Food Safety Evaluation Committee (FSEC). Regional KFDA offices will collect the samples and conduct the tests. For products already in the market (both domestic and imported), KFDA headquarters will designate a testing period for the respective products and the six regional KFDA offices will conduct the tests. For imported products, the six regional KFDA offices will test the respective products from the date when the proposed standards were announced until they are finalized.

If products exceed the recommended criteria, KFDA will send a notice to the importer or local manufacturer to inform them of KFDA's findings and recommend that either the imports be suspended or a voluntary recall take place. KFDA headquarters will also post their findings on KFDA's public website. Regional KFDA offices will conduct additional tests for products whose lot number is right before and after that of the product in question. Upon receipt of the notice from regional KFDA offices, importers and local manufacturers will follow KFDA's recommendation; setting a plan for voluntary recalls, conducting recalls, and destroying or diverting products in question for another purpose. Regional KFDA offices will monitor the actions taken by importers and local businesses and report it to the FSEC who will evaluate the results.

Food Safety Evaluation Committee

FSEC is chaired by the Deputy Commissioner of KFDA and consists of 35 people from academia and NGOs. FSEC reviews overall food safety issues including recommended criteria and discusses issues such as the establishment of new standards. Once they decide on the establishment of new standards, the Food Hygiene Evaluation Committee will set the specific standard for a particular product through the regular process.

Conclusion

KFDA is using this new program as a tool to enforce the recommended criteria as intermediary standards. In doing so, KFDA hopes to prevent harmful substances from causing problems prior to formalizing standards; however, they are circumventing the process whereby foreign trading partners or other interested parties are able to provide input on determining the recommended criteria.

Although actions taken by KFDA are called voluntary recalls, they are actually mandatory recalls. For this, KFDA plans to revise the Food Sanitation Act to create a legal basis for such actions against violations of recommended standards. A notice of all products that exceed the recommended criteria will be posted on KFDA's website, which may cause consumers to view these products negatively even though they have not violated KFDA's established standard.

Violation of recommended criteria will result in administrative action despite the fact that this program is ostensibly being called "recommended." Since these recommended criteria are not spelled out in the Food Code, as are established standards, it may be difficult for importers and manufacturers to know about them.

Appendix I

List of harmful materials subject to recommended criteria and monitoring in 2007

No	Food Category	Hazard Material	Recommended Criteria	Est. of Standard	Measures when exceeding recommended level ²⁾
1	Red pepper powder	Aflatoxin B1	10.0 μg/kg or below	Proposed	
2	Red pepper paste	Aflatoxin B1	10.0 μg/kg or below	40 000-	Recall to be
3	Bean paste (soybeans)	Aflatoxin B1	10.0 μg/kg or below		recommended
4	Soybean oil	Benzopyrene	2.0 μg/kg or below	Proposed	
5	Corn oil	Benzopyrene	2.0 µg/kg or below	on May	
6	Canola oil	Benzopyrene	2.0 μg/kg or below	2, 2007	
7	Rice bran oil	Benzopyrene	2.0 μg/kg or below		
8	Sesame oil	Benzopyrene	2.0 μg/kg or below		
9	Perilla oil	Benzopyrene	2.0 μg/kg or below		
10	Safflower oil	Benzopyrene	2.0 μg/kg or below		
11	Sunflower oil	Benzopyrene	2.0 μg/kg or below		
12	Cotton seed oil	Benzopyrene	2.0 μg/kg or below		Recall to be
13	Peanut oil	Benzopyrene	2.0 μg/kg or below		recommended
14	Palm oil	Benzopyrene	2.0 μg/kg or below		recommended
15	Coconut oil	Benzopyrene	2.0 μg/kg or below		
16	Mixed edible oil	Benzopyrene	2.0 μg/kg or below		
17	Processed oil & fat	Benzopyrene	2.0 μg/kg or below		
18	Shortening	Benzopyrene	2.0 μg/kg or below		
19	Margarine	Benzopyrene	2.0 μg/kg or below		
20	Red pepper seed oil	Benzopyrene	2.0 μg/kg or below		
21	Other edible oil & fat	Benzopyrene	2.0 µg/kg or below		
		Amoxicillin	0.05 mg/kg or below	Proposed on March	
22	Fisheries	Ampicillin	0.05 mg/kg or below	13, 2007	_
		Fefloxacin	0.05 mg/kg or below	To be proposed	
		Ofloxacin	0.05 mg/kg or below	in August 2007	
23	Tofu (bean curd	0 110	N	Proposed	
	(limited to airtight	Coliforms	Negative	on May	-
24	sealed products) Whole tofu (limited	1		17, 2007	
∠4	to airtight sealed				
	products)				
25	Fried tofu (limited	1			
	to airtight sealed				
	products)				

			1		I
26	Processed tofu				
	(limited to airtight				
	sealed products)				
27	Biscuits			To be	
28	Korean traditional			proposed	
	snacks	Ali una lina una	50 mm m/l/m om holovy	in second	
29	Snack foods	Aluminum	50 mg/kg or below	half of	-
30	Other			2007	
	confectioneries				
31	Dried noodles	Aluminum	100 mg/kg or below	To be	
				proposed	
				in second	-
				half of	
				2007	
32	EPA/DHA contained			To be	
	products			proposed	
33	Chlorella products			in second	
34	Spirulina products			half of	
35	Chitosan contained	Lead	10.8 μg/day or below	2007	
	products	Cadmium	3.0 μg/day or below		-
36	Chito	Total mercury	2.1 μg/day or below		
	oligosaccharide				
	contained products				
37	Glucosamine				
	contained products				
38	Flavored oil	Benzopyrene	2.0 μg/ml or below	Proposed	Recall to be
				on May	recommended
				17, 2007	
39	Products intended	Enterobacter	Negative	Proposed	Recall to be
	for infant and baby	sakazakii		on May	recommended
	younger than six			31, 2007	
	month old				
40	Polyethylene	Terephthalic	7.5 mg/l or below	Proposed	
	Terephthalate (PET)	acid		on June	
		Isophthalic	5.0 mg/l or below	1, 2007	
		acid			

¹⁾ Recommended criteria will be applied for products whose proposal to set standards has not been issued after the draft proposal to set standards is announced.

²⁾ Measures for all substances if a given product exceeds recommended criteria: The fact that the product exceeded recommended criteria will be released to public and additional tests for products whose lot number is right before and after that of the product in question will be conducted.

³⁾ Substances whose standards will be set and proposed in the future will be added to this list.